K112638

MAR - 9 2012

510(k) Summary

510(K) Owner:	Nova Biomedical Corporation
Registration Number:	1219029
Address:	200 Prospect St. Waltham, MA 02454 USA
Phone:	781-894-0800
Fax Number:	784-891-4806
Contact Person:	Paul W. MacDonald
Date Prepared:	12/19/2011
Proprietary Name:	Nova Max One Blood Glucose Monitoring System
Common Or Usual Name:	Blood Glucose Monitor
Classification Name:	System, Test, Blood Glucose, Over the Counter
Product Codes:	NBW, LFR, JJX
Predicate Device:	K070255 - Nova Max Blood Glucose Monitor System K051839 - FreeStyle Freedom Blood Glucose Monitoring System K092638 - FreeStyle Blood Glucose Test Strips
Device Description:	Nova Max One Blood Glucose Monitor The monitor is a hand-held testing device that works in conjunction with Nova Max One glucose-test strips to measure glucose in a whole blood sample. Monitor operation is self-prompting using three user interface buttons. In addition to measuring glucose, the monitor also stores patient test and quality control test data. The self-prompting menu system is navigated by means of a three-button keypad. It offers audible feedback for user inputs, and audible and/or visual feedback for prompts and user alerts.

	A "battery low" warning will alert the user to change the batteries. Battery charge state information is available on the "monitor status screen". The user can select the auto shutoff option to conserve power when the monitor is not in use. Test data and monitor setup information will be stored in a non-volatile format to prevent data loss. Nova Max One Blood Glucose Test Strips The test strips contain a reaction layer that contains a glucose-enzyme (greater than 1.0 IU) and ferricyanide as a mediator and will utilize glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) chemistry. The test strip is touched to a drop of blood to initiate the test process. The strip is designed such that when a drop of blood is touched to the end of the strip, the blood is drawn into the reaction space via capillary action. A simple one-step process provides a blood glucose result. Ten test strips will be provided with the meter kit and will also be available separately in vials of 25 strips. Historical data (on file at Nova Biomedical) shows minimal differences between lots of test strips produced over 2 years. As a result, test strips will now be manufactured to meet a single calibration code requirement, allowing for the elimination of a calibration step for the user when using the Nova Max One Blood Glucose Monitor. Control Solutions The control solutions are aqueous assayed solutions, containing buffered D-Glucose, viscosity-adjusting agent, preservatives and other non-reactive ingredients (dye). They contain no products of human origin. There are three levels of controls (1, 2 and 3). One level of control (Level 2) will be supplied with the monitor kit and all three levels will be available for sale separately from the monitor. These controls are manufactured by Nova Biomedical and identical to those cleared for market with the predicate Nova Max Blood Glucose Monitor System (K070255).
Intended Use:	The Nova Max One Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max One Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in fresh whole blood capillary samples obtained from the fingertip or alternative site testing (AST) on the forearm. AST on the forearm can be used only during steady-state blood glucose conditions. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns. Nova Max One Glucose Test Strips are intended for use only with the Nova Max One Blood Glucose Monitor for quantitative tests. The Glucose Monitor is intended to quantitatively measure glucose (sugar) in fresh capillary whole blood obtained from the finger tip or alternative site testing (AST) on the forearm. AST can be used only during steady-state blood glucose conditions. The Glucose Monitor is calibrated to provide plasma equivalent results to laboratory methods. Nova Max One Glucose Test Strips are for testing outside the body (in vitro diagnostic use only). The Monitor should only be used by a single user in the home and should not be shared by users. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns. Nova Max Control Solutions are intended for use with the Nova Max Blood Glucose Monitoring Systems as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Levels 1, 2, 3).

Summary of Technological Characteristics:	The Nova Max One Blood Glucose Monitor has the same fundamental scientific technology and the same intended use as the current on-market Nova Max Blood Glucose Monitor (K070255). The Nova Max One Blood Glucose Monitor is substantially equivalent to the Nova Max Glucose Monitor System. The Nova Max One Blood Glucose Monitor measures glucose electrochemically as described in K070255 (Nova Max Glucose Monitor System). In the same manner, the magnitude of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in whole blood and control solutions.
Comparison to Predicate Devices:	The Nova Max One Blood Glucose Monitor uses the same fundamental scientific technology and has the same intended use as the predicate Nova Max Blood Glucose Monitor (K070255).
Performance Studies:	The performance of the Nova Max One Blood Glucose Monitor was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that lay users can obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurements.
Conclusion:	Results of laboratory and clinical testing demonstrate that the performance of the Nova Max One Blood Glucose Monitor has the same intended uses, with similar technological characteristics and can produce results that are substantially equivalent to results obtained on the predicate devices. The system performs as intended and raises no new safety or effectiveness issues.

Comparison of Predicate Devices and Proposed device

Characteristic	Predicate K070255 - Nova Max Blood Glucose Monitor System	Predicate K051839 – Abbott FreeStyle Freedom Blood Glucose Monitoring System	Predicate K092638 – Abbott FreeStyle Blood Glucose Test Strips	Proposed Nova Max One Blood Glucose Monitor System
Measuring Range	20-600 mg/dL	20-500 mg/dL	20-500 mg/dL	20-600 mg/dL
Operating Principle	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor
Intended Use	The Nova Max Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Nova Max Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, forearm and palm.	The FreeStyle Freedom Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm, and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates or arterial blood.	The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm, and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates or arterial blood.	The Nova Max One Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max One Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in fresh whole blood capillary samples obtained from the fingertip or alternative site testing (AST) on the forearm. AST on the forearm can be used only during steady-state blood glucose conditions. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns.

Characteristic	Predicate K070255 - Nova Max Blood Glucose Monitor System	Predicate K051839 – Abbott FreeStyle Freedom Blood Glucose Monitoring System	Predicate K092638 – Abbott FreeStyle Blood Glucose Test Strips	Proposed Nova Max One Blood Glucose Monitor System
Hematocrit Range	25% to 60%	15% to 65%	15% to 65%	25% to 60%
Sample type	Capillary blood: fingertip, forearm, palm	Capillary blood: forearm, upper arm, hand, thigh, calf, or fingers	Capillary blood: forearm, upper arm, hand, thigh, calf, or fingers	Capillary blood: fingertip, forearm
Sample size	0.30 uL	0.30 uL	0.30 uL	0.40 uL
Glucose Units	mg/dL	mg/dL	mg/dL	mg/dL
Sample application	Test strip capillary draw	Test strip capillary draw	Test strip capillary draw	Test strip capillary draw
Handheld meter?	Yes	Yes	Yes	Yes
Data storage	Up to 400 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests
Analysis Time	5 seconds	5 seconds	4 seconds	4 seconds
Insulin Tracking	No	No	No	No.
Power source	3 volt coin cell battery	3 volt coin cell battery	3 volt coin cell battery	3 volt coin cell battery
Accessories:				
Controls:	Liquid	Liquid	Liquid	Liquid
Test Strips Active reagent:	Glucose Oxidase	Glucose Dehydrogenase - PQQ	Glucose Dehydrogenase - FAD	Glucose Dehydrogenase - FAD
Test Strip Calibration Coding	No User Input of Calibration code required	No User Input of Calibration coding required	Calibration coding required	No User Input of Calibration code required

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Nova Biomedical Corporation
c/o Paul W. MacDonald
Chief Quality and Regulatory Affairs Officer
200 Prospect Street
Waltham, MA 02454

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Re: k112638
Trade/Device Name: Nova Max One Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR, JJX
Dated: January 30, 2012
Received: February 1, 2012

Dear Dr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112638

Device Name: Nova Max One Blood Glucose Monitoring System

Indications for Use:

The Nova Max One Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max One Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in fresh whole blood capillary samples obtained from the fingertip or alternative site testing (AST) on the forearm. AST on the forearm can be used only during steady-state blood glucose conditions. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns.

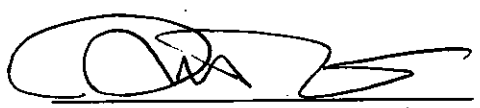
Nova Max One Glucose Test Strips are intended for use only with the Nova Max One Blood Glucose Monitor for quantitative tests. The Glucose Monitor is intended to quantitatively measure glucose (sugar) in fresh capillary whole blood obtained from the finger tip or alternative site testing (AST) on the forearm. AST can be used only during steady-state blood glucose conditions. The Glucose Monitor is calibrated to provide plasma equivalent results to laboratory methods. Nova Max One Glucose Test Strips are for testing outside the body (in vitro diagnostic use only). The Monitor should only be used by a single user in the home and should not be shared by users. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns.

Nova Max Control Solutions are intended for use with the Nova Max Blood Glucose Monitoring Systems as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Levels 1, 2, 3).

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112638